UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

CUSTOPHARM, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
FRESENIUS KABI USA, LLC,	)	Civil Action No: 6:21-CV-00148
	)	
Defendant.	)	
	)	

CUSTOPHARM, INC.'S DECLARATORY JUDGMENT COMPLAINT OF NONINFRINGEMENT

Plaintiff Custopharm, Inc. ("Custopharm"), by and through its undersigned counsel, files this Complaint for Declaratory Judgment of non-infringement of U.S. Patent Nos. 9,782,376 and 10,398,669 against Fresenius Kabi USA, LLC ("Fresenius Kabi" or "Defendant") as follows:

INTRODUCTION

1. This is a declaratory judgment action under 28 U.S.C. §2201(a) seeking a declaration of non-infringement of U.S. Patent Nos. 9,782,376 ("the '376 patent") (attached as **Exhibit A**) and 10,398,669 ("the '669 patent") (attached as **Exhibit B**). This action is related to and arises out of the same operative facts as Civil Action No. 20-1091 previously filed by Fresenius Kabi in this District against Custopharm for infringement of the '376 and '669 patents.

2. Custopharm's formulation cannot infringe any of the claims of the '376 and '669 patents because it uses different ingredients in a different way that results in an entirely different formulation, with different characteristics. Because Custopharm's Levothyroxine Product

formulation lacks critical claim elements required by the ’376 and ’669 patents, it cannot infringe either of those patents. Fresenius Kabi cannot prove otherwise.

3. Custopharm offered, on multiple occasions, to provide the formulation for its 505(b)(2) NDA Product to counsel for Fresenius Kabi on an outside counsel eye’s only basis. Fresenius Kabi rejected Custopharm’s offer. Without knowing what Custopharm’s formulation was much less whether it infringed, on October 30, 2020, Fresenius Kabi filed lawsuits against Custopharm in three U.S. District Courts: the U.S. District Court for the Western District of Texas (1:20-cv-1091), the District of New Jersey (2:20-cv-15342), and the District of Colorado (1:20-cv-03254) alleging patent infringement of the ’376 and ’669 patents based on Custopharm’s submission of a 505(b)(2) New Drug Application (“NDA”) to the United States Food and Drug Administration (“FDA”) seeking approval to manufacture and sell Custopharm’s levothyroxine sodium solution product.

4. On December 28, 2020, Custopharm voluntarily, on an outside counsel eyes only basis, provided counsel for Fresenius Kabi with a copy of Custopharm’s NDA, which includes the formulation for Custopharm’s Levothyroxine product and conclusively demonstrates that Custopharm’s formulation cannot infringe the ’376 or ’669 patents.

5. Nevertheless, Fresenius Kabi has repeatedly refused to provide any basis for its infringement allegations, while maintaining its multiple litigations against Custopharm seeking to delay Custopharm’s ability to launch its competing liquid Levothyroxine product. Through its actions, Fresenius Kabi is causing substantial injury to Custopharm in seeking to prevent the marketing of a competing levothyroxine liquid product..

6. Because Custopharm is a Texas Corporation, Fresenius Kabi’s Complaint filed in the Western District of Texas was the only one of the three actions filed by Fresenius Kabi filed in

a proper venue under 28 U.S.C. §1400(b). *See Valeant Pharms. N. Am. LLC, et. al. v. Mylan Pharms., Inc., et al.,* 978 F.3d 1374, 1375 (Fed. Cir. 2020). Fresenius Kabi recently litigated against Custopharm in the Western District of Texas and knew that was and is a proper venue for its action. *See Fresenius Kabi USA, LLC and Fresenius Kabi Deutschland GMBH v. Custopharm, Inc.,* C.A. 18-0065 (W.D.Tex)). Custopharm has filed Motions to Dismiss for improper venue in both the District of New Jersey and the District of Colorado. On January 26, 2021, Magistrate Judge Hegarty issued his Recommendation of United States Magistrate Judge that Custopharm's Motion to Dismiss the Colorado Action for improper venue be granted and that the case be transferred to the Western District of Texas. **Exhibit C** (*Recommendation of United States Magistrate,* Case No. 1:20-cv-03254 (D. Colo.), ECF 43). Fresenius Kabi subsequently appealed that Recommendation. Custopharm's Motion to Dismiss is still pending in the District of New Jersey.

7. Instead of proceeding with the action filed in this District to litigate the merits of the case, on January 27, 2021, the day after the Magistrate Judge in Colorado recommended that the Colorado action be transferred to this District, Fresenius Kabi voluntarily dismissed its Complaint pending in the Western District of Texas without ever serving it and without informing this Court of the Magistrate Judge's recommendation that the case be transferred here. **Exhibit D** (*Notice of Voluntary Dismissal,* Case No. 1:20-cv-01091 (W.D. Tex.), ECF 9).

8. Fresenius Kabi's actions of dismissing the litigation it filed in the Western District of Texas, a venue all parties agree is proper, but maintaining the litigations in two districts where venue is improper is delaying the resolution of the merits of this case and preventing Custopharm from removing the cloud that Fresenius Kabi is trying to create with its objectively baseless assertion that Custopharm's 505(b)(2) Product infringes the '376 and '669 patents.

THE PARTIES

9. Custopharm is a Texas corporation with a principal place of business at 2325 Camino Vida Roble, Ste. B, Carlsbad, California 92011.

10. On information and belief, Fresenius Kabi is a corporation organized and existing under the laws of the state of Delaware, having its corporate headquarters at Three Corporate Drive, Lake Zurich, Illinois 60047.

JURISDICTION AND VENUE

11. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 based upon an actual controversy between the parties for a declaration that Custopharm's Levothyroxine product that is subject of Custopharm's 505(b)(2) New Drug Application does not and will not infringe the '376 and/or '669 patents.

12. This Court has jurisdiction over Custopharm's declaratory judgment claims pursuant to 28 U.S.C. § 2201 *et seq.* based on Fresenius Kabi's suits against Custopharm for patent infringement, thereby giving rise to an actual case or controversy under 28 U.S.C. §§ 2201 and 2202.

13. A substantial controversy of sufficient immediacy and reality exists between the parties to warrant the issuance of a declaratory judgment because Fresenius Kabi has asserted the '376 and '669 patents against Custopharm in this District, in the District of New Jersey, and in the District of Colorado.

14. This Court has personal jurisdiction over Fresenius Kabi because it has a registered agent, Corporation Service Company d/b/a CSC, in Austin, Texas for service of process located at 211 E. 7th Street, Suite 620, Austin, TX 78701.

15. This Court has personal jurisdiction over Fresenius Kabi, at least because it has purposefully availed itself of the privilege of conducting activities within this District and has invoked the benefits and protections of its laws by suing Custopharm to try to enforce the same patents at issue in this Declaratory Judgment Action, and through its continuous and systematic contacts with the state of Texas, including on information and belief conducting substantial and regular business therein through marketing and sales of pharmaceutical products in Texas including but not limited to its own levothyroxine liquid product.

16. This Court has personal jurisdiction over Fresenius Kabi because Fresenius Kabi has previously submitted to the jurisdiction of this Court and has further availed itself of this Court by filing lawsuits in this jurisdiction.

17. Venue is proper in this District under 28 U.S.C. §§1391(b), (c), and/or 1400(b).

THE PATENTS-IN-SUIT

18. On its face the '376 patent entitled "Levothyroxine Liquid Formulations" indicates that it was issued by the United States Patent and Trademark Office on October 10, 2017 and is assigned to Fresenius Kabi USA, LLC. **Exhibit A**.

19. The '376 patent was filed on December 1, 2016 and assigned Application No. 15/366,864 ("the '864 Application"). The '864 Application was originally filed with 30 claims of which claims 1, 18, and 24 were the independent claims. Original claims 1, 18 and 24 are reproduced here:

> 1. A liquid formulation comprising levothyroxine or a pharmaceutically acceptable salt thereof; tromethamine; sodium iodide; and water; wherein the formulation has a pH of about 9.0 to about 11.5.
>
> 18. A liquid formulation comprising (a) levothyroxine or a pharmaceutically acceptable salt thereof in a concentration of about 20 mcg/mL to about 100 mcg/mL; (b) tromethamine in a concentration of about 5 mg/mL to about 20 mg/mL; (c) sodium

> iodide in a concentration of about 100 mcg/mL to about 300 mcg/mL; (c) sodium chloride; and (d) water; wherein the formulation has a pH of about 9.8 to about 10.8.
>
> 24. A liquid formulation comprising (a) levothyroxine sodium in a concentration of about 20 mcg/mL to about 100 mcg/mL; (b) tromethamine in a concentration of about 10 mg/mL; (c) sodium iodide in a concentration of about 140 mcg/mL; (c) sodium chloride; and (d) water; wherein the formulation has a pH of about 9.8 to about 10.8.

Exhibit E at pp. 22-24.

20. Each of the original claims of the '864 Application required that the liquid formulation include tromethamine.

21. Each of the original claims of the '864 Application required that the liquid formulation include sodium iodide.

22. Each of the original claims of the '864 Application required that the liquid formulation have a pH of 9.0 or higher.

23. On February 27, 2017, the United States Patent and Trademark Office ("USPTO") issued a first Office Action. In the Office Action the Examiner rejected each of the pending claims as being unpatentable over US2009/0270507 (the "'507" or "Pierres") in view of Remington Pharmaceutical Science, 17th ed., 1985. **Exhibit F** at Office Action, dated 2/27/17, pp. 2-3. In the Office Action, the Examiner stated that the "'507 teaches a liquid levothyroxine composition comprising 0.1 mg/ml to 2 mg/ml of levothyroxine, sodium iodide (iodide donor), water, buffer and pH to be from 9-10." **Exhibit F** at Office Action, dated 2/27/17, p. 2. The Examiner continued that the "'507 does not expressly teach the use of tromethamine and sodium chloride." **Exhibit F** at Office Action, dated 2/27/17, p. 3.

24. The Examiner concludes the Office Action stating:

> It would have been obvious to one of ordinary skill in the art to formulate a liquid levothyroxine composition by employ the herein claimed tonicity agent, sodium chloride, and tromethamine as buffering agent. It would have been obvious

> to one of ordinary skill in the art to employ the herein claimed amount of the components.
>
> One of ordinary skill in the art would have been motivated to formulate a liquid levothyroxine composition by employ the herein claimed tonicity agent, sodium chloride, and tromethamine as buffering agent. Since sodium chloride and tromethamine are well known to be tonicity adjust agent and buffering agent respectively, selecting these agents are considered obvious as the skilled artisan selecting the obvious conventional agents for achieving the tonicity and pH desired, absent evidence of demonstrating the criticality of using both agents.
>
> One of ordinary skill in the art would have been motivated to employ the herein claimed amount of the components. The optimization of result effect parameters (e.g., dosage range and weight percentage of the excipients) is obvious as being within the skill of the artisan. The optimization of known effective amounts of known active agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect.

Exhibit F at Office Action, dated 2/27/17, pp. 3-4.

25. On May 30, 2017, Fresenius Kabi responded to the Office Action by arguing "Pierres fails to teach that the buffer can be tromethamine. A person of ordinary skill in the art, in seeking to modify the composition disclosed by Pierres, would be led away from tromethamine as a suitable buffer. Tromethamine (also known as Trizma) has a pKa of 8.20 at 20° C. The pKa of the buffer taught by Pierres is approximately 1.3 orders of magnitude greater than the pKa of tromethamine (i.e., 9.5 v. 8.2)." **Exhibit G** at pp.7-8 (internal citations omitted).

26. Fresenius Kabi also argued that "Examples 2 and 3 of the present application provides evidence for the surprising and unexpected stability of exemplary formulation comprising levothyroxine sodium, sodium iodide, and tromethamine." **Exhibit G** at p.8.

27. Fresenius Kabi also amended the independent claims by including a limitation that the "formulation is stable for at least 12 months at 25 ± 2° C," and by further limiting the claims to particular amounts of tromethamine ("about 1 mg/mL to about 50 mg/mL") and sodium iodide

("about 10 mcg/mL to about 500 mcg/mL") necessary to achieve this stability, which Fresenius Kabi asserted was unexpected. **Exhibit G** at pp. 2-4, 8.

28. On June 19, 2017, a Notice of Allowance issued stating "the herein claimed composition comprising levothyroxine with tromethamine, in the herein claimed amount, and increased stability is not taught or fairly suggested by the prior art. Specifically, the amount of tromethamine cannot be used as pH adjusting agents and there is no other motivation to adjust the pH of the liquid formulation to the herein claimed range." **Exhibit H** at Reasons for Allowance, p. 2.

29. The '376 patent issued with 30 claims of which 1, 18, and 24 are the only independent claims. Claims 1, 18, and 24 are reproduced here:

> 1. A liquid formulation comprising levothyroxine or a pharmaceutically acceptable salt thereof; about 1 mg/mL to about 50 mg/mL of tromethamine; about 10 mcg/mL to about 500 mcg/mL of sodium iodide; and water; wherein the formulation has a pH of about 9.0 to about 11.5, and wherein the formulation is stable for at least 12 months at 25 ± 2° C.
>
> 18. A liquid formulation comprising (a) levothyroxine or a pharmaceutically acceptable salt thereof in a concentration of about 20 mcg/mL to about 100 mcg/mL; (b) tromethamine in a concentration of about 5 mg/mL to about 20 mg/mL; (c) sodium iodide in a concentration of about 100 mcg/mL to about 300 mcg/mL; (c) sodium chloride; and (d) water; wherein the formulation has a pH of about 9.8 to about 10.8, and wherein the formulation is stable for at least 12 months at 25 ± 2° C.
>
> 24. A liquid formulation comprising (a) levothyroxine sodium in a concentration of about 20 mcg/mL to about 100 mcg/mL; (b) tromethamine in a concentration of about 10 mg/mL; (c) sodium iodide in a concentration of about 140 mcg/mL; (c) sodium chloride; and (d) water; wherein the formulation has a pH of about 9.8 to about 10.8, and wherein the formulation is stable for at least 12 months at 25 ± 2° C.

Exhibit A.

30. Each claim of the '376 patent requires that the liquid formulation include tromethamine.

31. Each claim of the ’376 patent requires that the liquid formulation include sodium iodide.

32. Each claim of the ’376 patent requires that the liquid formulation have a pH of 9.0 or higher.

33. Through Fresenius Kabi’s statements and actions in the Patent Office to overcome the prior art and to obtain allowance of the ’376 Patent, Fresenius Kabi has limited the scope of its claims to formulations containing the claimed concentrations of tromethamine, sodium iodide and having pH ranges between about 9.0 to about 11.5, including about 9.8 to about 10.8, as necessary to achieve the claimed stability levels.

34. On its face the ’669 patent entitled “Levothyroxine Liquid Formulations” indicates that it was issued by the United States Patent and Trademark Office on September 3, 2019 and is assigned to Fresenius Kabi USA, LLC. **Exhibit B.**

35. The ’669 patent was filed on September 11, 2017 and assigned Application No. 15/700,258 (“the ’258 Application”). The ’258 Application was originally filed with 20 claims of which claim 1 was the sole independent claim. Original claim 1 is reproduced here:

> 1. A liquid formulation comprising levothyroxine or a pharmaceutically acceptable salt thereof; a stabilizing agent; not more than 2% liothyronine (T3); and water; wherein the formulation is stable for at least 12 months at 25±2º C.

Exhibit I at p. 22.

36. On May 3, 2018, the USPTO issued an Office Action rejecting each of the 20 claims in the ’258 Application as being unpatentable under 35 U.S.C. 103 over US2009/0270507 (referred to as “’507” or “Pierres”) in view of Remington Pharmaceutical Science, 17th ed., 1985 which were also made of record during the prosecution of the ’376 patent. **Exhibit J** at Office Action, dated 5/3/18, pp. 2-3. In the office action the Examiner notes that “’507 does not expressly teach

the use of tromethamine and sodium chloride." **Exhibit J** at Office Action, dated 5/3/18, p.2. The Examiner also rejected the claims of the '258 Application "on the ground of nonstatutory double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 9,782,376 ('376). Although the claims at issue are not identical, they are not patentably distinct from each other because '376 teaches a levothyroxine composition in which the scope of '376 is narrower than that of the instant case. This is an anticipatory type of obviousness double patenting rejection." **Exhibit J** at Office Action, dated 5/3/18, pp. 5-6.

37. On September 4, 2018, Applicants filed a *Terminal Disclaimer to Obviate a Double Patenting Rejection Over a "Prior" Patent*. **Exhibit K.**

38. On September 4, 2018, Applicants responded to the Office Action. Applicants cancelled claim 16 and amended claim 1 as follows:

> A liquid formulation comprising levothyroxine or a pharmaceutically acceptable salt thereof; a stabilizing agent; not more then 2% liothyronine (T3); and water; wherein the formulation ~~is stable for at least~~ retains at least about 95% of the initial concentration of levothyroxine or pharmaceutically acceptable salt thereof after storage for 12 months at 25 ±2ºC, and retains at least about 95% of the initial concentration of levothyroxine or pharmaceutically acceptable salt thereof after storage for 2 months at 40 ±2ºC.

Exhibit L at pp. 2-3.

39. On November 9, 2018, the USPTO issued a Final rejection rejecting claims 1-5, 7-15, and 17-20. The claims were rejected under 35 USC § 112, first paragraph "because the specification, while being enabling for tromethamine, does not reasonably provide enablement for other stabilizing agents that give rise to the stability of retaining 'at least about 95% of the initial concentration of levothyroxine after storage for 2 months at 40 ±2ºC'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the specification

fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation" **Exhibit M** at Office Action, dated 11/9/18, pp. 2-3.

40. The Examiner objected to claim 6 as being dependent on a rejected claim. **Exhibit M** at Office Action, dated 11/9/18,p. 5. The Examiner stated that it "would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." **Exhibit M** at Office Action, dated 11/9/18,p. 5. Claim 6 recited "The formulation of claim 5, wherein the amine is tromethamine which is present at a concentration of about 1 mg/mL to about 50 mg/mL." **Exhibit L** at p. 2.

41. On April 8, 2019, Applicants responded to the Final Office Action by amending claim 1 to specifically recite tromethamine as follows:

> A liquid formulation comprising levothyroxine or a pharmaceutically acceptable salt thereof; a stabilizing agent comprising tromethamine; not more than 2% liothyronine (T3); and water; wherein the formulation retains at least about 95% of the initial concentration of levothyroxine or pharmaceutically acceptable salt thereof after storage for 12 months at 25 ±2ºC, and retains at least about 95% of the initial concentration of levothyroxine or pharmaceutically acceptable salt thereof after storage for 2 months at 40 ±2ºC.

Exhibit N at p. 2.

42. On April 17, 2019, a Notice of Allowance issued stating, *inter alia,* "[t]he following is an examiner's statement of reasons for allowance: the incorporation of tromethamine into the levothyroxine composition…." **Exhibit O** at Reasons for Allowance, p. 2.

43. The '669 patent issued with 17 claims of which claim 1 is the sole independent claim. Claim 1 is reproduced here:

> 1. A liquid formulation comprising levothyroxine or a pharmaceutically acceptable salt thereof; a stabilizing agent comprising tromethamine; not more than 2% liothyronine (T3); and water; wherein the formulation retains at least about 95% of the initial concentration of levothyroxine or pharmaceutically acceptable salt thereof after storage for 12 months at 25±2º C, and retains at least about 95% of the initial concentration of

levothyroxine or pharmaceutically acceptable salt thereof after storage for 2 months at 40±2° C.

Exhibit B.

44. Each claim of the '669 patent recites a liquid levothyroxine formulation.

45. Each claim of the '669 patent requires that the liquid formulation include tromethamine.

46. The '669 patent is a continuation of the '376 patent and shares a common specification.

47. Through Fresenius Kabi's statements and actions in the Patent Office to obtain allowance of the '669 Patent, Fresenius Kabi has limited the scope of its claims to formulations containing tromethamine.

FACTUAL BACKGROUND

48. Custopharm, Inc. is the current owner of FDA NDA No. 214253 submitted to FDA pursuant to §505(b)(2) of the Federal Food, Drug and Cosmetic Act, seeking approval for the commercial manufacture, use, sale, offer for sale, and/or importation of a unique liquid formulation of levothyroxine sodium injection, 100 mcg/1mL ("Custopharm's 505(b)(2) Product").

49. Custopharm's 505(b)(2) Product's formulation was produced to Fresenius Kabi's counsel on an Outside Counsel Eyes' Only basis. CPLEVO_ANDA0000242.

50. Custopharm's 505(b)(2) Product does not include tromethamine.

51. Custopharm's 505(b)(2) Product does not include sodium iodide.

52. Custopharm's 505(b)(2) Product does not have a pH of 9.0 or higher.

53. Custopharm's NDA No. 214253 indicates that NDA No. 202231 is the reference drug for Custopharm's 505(b)(2) Product. CPLEVO_ANDA0000245. The FDA publication,

Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book" lists U.S. Patent Nos. 9,006,289; 9,168,238; and 9,168,239 in connection with the reference drug for Custopharm's 505(b)(2) Product. As required by Section 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act, 21 CFR 314.50, Custopharm included a certification in NDA No. 214253 that U.S. Patent Nos. 9,006,289; 9,168,238; and 9,168,239 are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Custopharm's 505(b)(2) Product.

54. As required by Sections 505(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(b)(3)(B)(i)), as amended by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act, Pub. L. No. 108-183 Stat. 2066 (2003), Custopharm provided notice to Fresenius Kabi that U.S. Patent Nos. 9,006,289; 9,168,238; and 9,168,239 are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Custopharm's 505(b)(2) Product.

55. To date, Fresenius Kabi has not asserted U.S. Patent Nos. 9,006,289; 9,168,238; and/or 9,168,239 against Custopharm, but did file three Complaints in three separate Districts alleging infringement of the '376 and'669 patents.

56. The '376 and '669 patents are not listed in the Orange Book in connection with the reference drug for Custopharm's 505(b)(2) Product.

57. Prior to Fresenius Kabi filing the three Complaints against Custopharm, Custopharm offered to provide the formulation for its 505(b)(2) NDA Product to counsel for Fresenius Kabi on an outside counsel eye's only basis. **Exhibits P-Q**.

58. Fresenius Kabi's counsel refused to accept Custopharm's formulation and instead filed the three Complaints without knowing the formulation of Custopharm's 505(b)(2) NDA Product.

59. In December 2020, Custopharm again voluntarily offered to produce its 505(b)(2) NDA, including the formulation for its 505(b)(2) Product to counsel for Fresenius Kabi on an outside counsel eye's only basis. **Exhibit R**. Counsel for Fresenius Kabi agreed to these terms.

60. Because Custopharm is a Texas Corporation, Fresenius Kabi's Complaint filed in the Western District of Texas was the only one of the three actions filed by Fresenius Kabi that was filed in a proper venue under 28 U.S.C. §1400(b). *See Valeant Pharms. N. Am. LLC, et. al. v. Mylan Pharms., Inc., et al.,* 978 F.3d 1374, 1375 (Fed. Cir. 2020). Fresenius Kabi voluntarily dismissed the pending Complaint in this District, but maintains the actions in two Districts where venue is improper, Custopharm seeks a judicial declaration that the '376 and '669 patents would not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Custopharm's 505(b)(2) Product.

61. Through its actions of filing three lawsuits on patents that Fresenius Kabi knows or should know are not infringed by Custopharm's NDA product formulation and that no reasonable person could believe infringe the claims of the '376 and '669 patents, Fresenius Kabi is seeking to improperly to expand the scope of its patent to encompass objectively noninfringing formulations and to use legal proceedings to restrain trade and prevent or delay competition in the market for liquid levothyroxine.

62. As the only current marketer of a liquid levothyroxine formulation in the U.S., Fresenius Kabi has market power in the market for liquid levothyroxine.

COUNT I
(Declaration of Non-Infringement of the '376 Patent)

63. Custopharm realleges and incorporates by reference paragraphs 1-62 of these Counterclaims.

64. Each claim of the '376 patent requires a specific concentration of tromethamine.

65. Each claim of the '376 patent requires a specific concentration of sodium iodide.

66. Each claim of the '376 patent requires the resulting claimed formulation have a pH of 9.0 or higher.

67. Custopharm's 505(b)(2) Product formulation does not include each and every element recited in the claims of the '376 patent.

68. Custopharm's 505(b)(2) Product formulation is missing a number of required limitations of the '376 patent claims, including for example, tromethamine, sodium iodide and pH of 9.0-11.5 and 9.8-10.8.

69. Custopharm's 505(b)(2) Product is substantially different from the formulations claimed in the '376 patent including for example in terms of the ingredients in the formulation, the amounts of those ingredients, the functions of those ingredients, the ways they interact and the resulting properties of the formulation including the pH of the formulation.

70. Custopharm's 505(b)(2) Product does not include tromethamine.

71. Custopharm's 505(b)(2) Product does not include sodium iodide.

72. Custopharm's 505(b)(2) Product does not have a pH of 9.0 or higher.

73. Custopharm's 505(b)(2) Product does not have tromethamine in the claimed concentrations.

74. Custopharm's 505(b)(2) Product does not have sodium iodide in the claimed concentrations.

75. As a result of statements made and positions taken by Fresenius Kabi during prosecution to obtain allowance of the claims of the '376 patent, Fresenius Kabi is estopped from trying to expand the scope of this patent to include levothyroxine formulations that do not include tromethamine and sodium iodide, in the amounts claimed and having a pH range outside of 9.0 to 11.5.

76. Fresenius Kabi cannot expand the scope of the claims of the '376 patent to encompass Custopharm's 505(b)(2) Product because the claims would then read on the prior art, including for example, U.S. 2018/0214374, and would not be supported or enabled by the specification and therefore would be invalid under 35 U.S.C. §§ 102, 103 and/or 112.

77. The manufacture, use, sale, offer for sale, or importation into the United States of the levothyroxine sodium injection, 100 mcg/1mL product that is the subject of NDA No. 214253 has not infringed, does not infringe, and would not, if marketed, infringe, directly or under doctrine of equivalents, any valid or enforceable claim of the '376 patent.

78. Fresenius Kabi will be unable to prove that the levothyroxine sodium injection, 100 mcg/1mL product described in NDA No. 214253 meets each and every limitation of any valid or enforceable claim of the '376 patent and therefore will not be able to prove that Custopharm's 505(b)(2) product that is the subject of NDA No. 214253 infringes the '376 patent.

79. Custopharm is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation into the United States of the levothyroxine sodium injection, 100 mcg/1mL product that is the subject of NDA No. 214253 has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '376 patent.

COUNT II
(Declaration of Non-Infringement of the '669 Patent)

80. Custopharm realleges and incorporates by reference paragraphs 1-79 of these Counterclaims.

81. Each claim of the '669 patent requires tromethamine.

82. Additionally, dependent claims of the '669 patent further require sodium iodide, including sodium iodide in a concentration of about 10 mcg/mL to about 500 mcg/mL, a pH of 9.0-11.5 and 9.8-10.8, and a concentration of about 1 mg/mL to about 50 mg/mL of tromethamine.

83. Custopharm's 505(b)(2) Product formulation is missing a number of required limitations of the '669 patent claims, including for example tromethamine, sodium iodide, the claimed concentrations of tromethamine and sodium iodide, and pH of 9.0-11.5 and 9.8-10.8.

84. Custopharm's 505(b)(2) Product is substantially different from the formulations claimed in the '669 patent including for example in terms of the ingredients contained in the formulation, the amounts of those ingredients, the functions of those ingredients, the ways they interact and the resulting properties of the formulation including the pH of the formulation.

85. Custopharm's 505(b)(2) Product does not include tromethamine.

86. Custopharm's 505(b)(2) Product does not include sodium iodide.

87. Custopharm's 505(b)(2) Product does not have a pH of 9.0 or higher.

88. Custopharm's 505(b)(2) Product does not have tromethamine in a concentration of about 1 mg/mL to about 50 mg/mL.

89. Custopharm's 505(b)(2) Product does not have sodium iodide in a concentration of about 10 mcg/mL to about 500 mcg/mL.

90. As a result of statements made and positions taken by Fresenius Kabi during prosecution to obtain allowance of the claims of the '669 patent, Fresenius Kabi is estopped from trying to expand the scope of this patent to include levothyroxine formulations that do not include tromethamine.

91. Fresenius Kabi cannot expand the scope of the claims of the '669 patent to encompass Custopharm's 505(b)(2) Product because the claims would then read on the prior art, including for example, U.S. 2018/0214374, and would not be supported or enabled by the specification and therefore would be invalid under 35 U.S.C. §§ 102, 103 and/or 112.

92. Custopharm's 505(b)(2) Product formulation does not include each and every element recited in the claims of the '669 patent.

93. The manufacture, use, sale, offer for sale, or importation into the United States of the levothyroxine sodium injection, 100 mcg/1mL product that is the subject of NDA No. 214253 has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '669 patent.

94. Fresenius Kabi will be unable to prove that the levothyroxine sodium injection, 100 mcg/1mL product described in NDA No. 214253 meets each and every limitation of any valid or enforceable claim of the '669 patent and therefore will not be able to prove that Custopharm's 505(b)(2) product that is the subject of NDA No. 214253 infringes the '669 patent.

95. Custopharm is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation into the United States of the levothyroxine sodium injection, 100 mcg/1mL product that is the subject of NDA No. 214253 has not infringed, does not infringe, and would not, if marketed, infringe, directly or under doctrine of equivalents, any valid or enforceable claim of the '669 patent.

PRAYER FOR RELIEF

WHEREFORE, Custopharm respectfully requests that this Court enter a Judgment and Order in their favor and against Counter-Defendant as follows:

a. Declaring that the manufacture, use, sale, offer for sale, or importation into the United States of the levothyroxine sodium injection, 100 mcg/1mL product described in NDA No. 214253 has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '376 patent or in the alternative the claims of the '376 patent are invalid.

b. Declaring that the manufacture, use, sale, offer for sale, or importation into the United States of the levothyroxine sodium injection, 100 mcg/1mL product described in NDA No. 214253 has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '669 patent or in the alternative the claims of the '669 patent are invalid.

c. Awarding Custopharm costs, expenses, and reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

d. Awarding such other relief that the Court deems just and proper under the circumstances.

Dated: February 16, 2021

Respectfully submitted,

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